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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,949	09/10/2001	Johan Stenflo	003300-816	9510

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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/890,949

Applicant(s)

STENFLO, JOHAN

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 19-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14, 19-23 and 26 is/are allowed.
- 6) ☐ Claim(s) 15-16, 24-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendment filed on 10/15/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 17-18 cancelled.
2. Currently, claims 1-16, 19-26 are under examination.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 15-16, 24-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

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The instant invention directs to a monoclonal antibody having specific affinity for both (1) a complex between a serine proteinase with a serine proteinase inhibitor (2) a cleaved and uncomplexed form of said serine proteinase inhibitor and (3) no affinity for said inhibitor in its uncleaved and complexed form. However, applicant also recites using the above antibody for diagnosis of various thrombosis, arterial thrombosis, embolism, coronary infraction, disseminated intravascular coagulation, or lupus anticoagulants.

The above mentioned pathological diseases are patently distinct in various aspects, including etiology, pathological development, mechanism, ...etc. In light of the specification, applicant merely provides guidance and instructions as to how to (1) make the antibodies; (2) characterize the said antibody (See pages 14-19). Particularly, the only experimental data, i.e. Figure 1-3, merely show the characteristics of the antibody, e.g. having affinity to APC-PCI complex and cleaved PCT, but not to the native (uncleaved uncomplex) PCI. There is no detailed information, instruction, or data as to direct one ordinary skilled in the art as to relate the above mentioned diseases to the use of the particular antibody recited in this invention. For example, no clinical data concerning any of the diseases are presented. No healthy control samples are used to conduct the assay. No knowledge of how many samples, e.g. for statistical analysis, is necessary to conclude there is a nexus connection between those diseases and the monitoring using the instant recited monoclonal antibody. No method step(s) is shown as to the relationship to the measurement of APC-PCI and cleaved form of PCT with the condition of the recited diseases. For instance, does every disease share the same feature, e.g. increase or decrease amount of the APC-PCI or cleaved PCI? Most importantly, if the antibody is capable of "diagnosing" the above mentioned diseases, how can one artisan in the field distinguish which one of the recited diseases is really the target one?

In view of the aforementioned lack of predictability in the art, undue experimentation would be required to practice the claimed methods with a reasonable expectation of success, absent a specific and detailed description in the applicant's specification of how to effectively practice the recited method and absent working examples.

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 4, line 5, "HGKI" is vague and indefinite. Applicant needs to spell the full name of this protein.

With respect to claim 20, line 5, "HGKI" is vague and indefinite. Applicant needs to spell the full name of this protein.

Response to Applicant's Arguments

5. Scope of enablement rejection under 35 USC §112, first paragraph, as set forth in the previous Office Action is withdrawn.

Allowable Subject Matter

6. Claims 1-14, 19-23, 26 are allowed.

7. The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or fairly teaches a monoclonal antibody having specific affinity for (i) a complex of serine proteinase and serine proteinase inhibitor, (ii) a cleaved an uncomplexed form of serine inhibitor, while having no specific affinity for the proteinase inhibitor in its uncleaved and active form. The closest prior art is the reference of Laurell et al. (Thrombosis and Haemostasis (1988) Vol. 60: pages 334-339). Laurell et al. teach an antibody (M11-15) can bind to the complex of serine proteinase with proteinase inhibitor and uncleaved active serine

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proteinase inhibitor (See Figure 8, both upper and lower part, lane 6)(emphasis added).

However, the antibody does not have affinity to the cleaved and uncomplexed form of proteinase inhibitor.

Conclusion

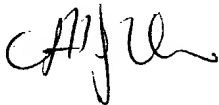
8. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

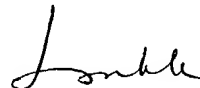
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner



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December 28 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

1/10/05